REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 1-4 are pending and are under consideration. Claim 1 has been amended as explained below. No new matter has been added as a result of these amendments.

Applicants thank the Examiner for withdrawing the objection to the disclosure for informalties made in the previous Office Action. Applicants thank the Examiner for withdrawing the objection to claim 1 made in the previous Office Action. Applicants thank the Examiner for withdrawing the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention, made in the previous Office Action. Applicants thank the Examiner for withdrawing the rejection of claims 1-4 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention, made in the previous Office Action.

Rejection of Claims 1-4 Under 35 U.S.C. § 112, First Paragraph

Claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner maintains the rejection made in the previous Office Action and states that the specification has not evidenced an enabling disclosure in which a definitive

prostate cancer diagnosis can be made with any complement of SEQ ID NO: 4, nor the full-length sequence of SEQ ID NO: 4. The Examiner also states that the specification continues to be remiss of support enabling the skilled artisan to implement SEQ ID NO: 4 or undefined complements thereof in any form of cancer diagnosis and there is no disclosure designating which complements or what criteria is used for discerning which nucleic acid residues would be effective in any diagnostic method. Applicants respectfully traverse the rejection.

The hybridization process is known and well-defined in the art as discussed in Applicants' previous response. The significance of epitopes (page 45 of the specification), the detection of PS190 antibodies (pages 45 and 46) the expression of mRNA corresponding to SEQ ID NO: 4 indicating the presence of prostate disease (Examples 4-6 and 8) and other indications of prostate diseases using SEQ ID NO: 4 and complements thereof were discussed in Applicants' previous response. These arguments are incorporated herein.

While Applicants traverse the Examiner rejection, the claims have been amended in order to expedite prosecution of the present application. Specifically, claim 1 has been amended to recite "said polynucleotide consists a sequence selected from the group consisting of SEQ ID NO: 4 and complements thereof". Therefore, the claims no longer read on any polynucleotide comprising SEQ ID NO: 4 and any complements thereof. The claims now require that the polynucleotide consists of a specific and definitive sequence and its complements.

The Examiner's attention is also directed to *Noelle v. Lederman* (CAFC, January 20, 2004, USPQ2nd Vol. 69, No. 7, 1481-1544) where the Court held that a claim directed to an antibody which is capable of binding to a particular antigen has sufficient support in the written description that discloses "fully characterized" antigens. The Court stated that if an applicant has disclosed fully characterized antigens, either by structure, formula, chemical name, physical properties, or by deposit in a public depository, then the applicant can claim the antibody by its affinity to the described antigen.

Applicants' disclosure describes methods such as hybridization using the claimed polynucleotides for detecting prostate diseases. Additionally, Applicants' specification discloses the exact sequence containing the exact nucleotides of the claimed polynucleotides, SEQ ID NO: 4. This equates to the structure, formula and chemical name as discussed in *Noelle*. Furthermore, the polynucleotide hybridization of the present invention involves affinity of one polynucleotide toward another, which is similar to the affinity of the antigen to the antibody that *Noelle* indicates to be significant and cannot be ignored.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, with respect to enablement of these features.

Rejection of Claims 1-4 Under 35 U.S.C. § 101

Claims 1-4 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well established utility. Specifically, the Examiner maintains the rejection made in the previous Office Action and states that "Applicants' arguments suggest that one of ordinary skill in the art can use any arbitrary fragment of SEQ ID NO: 4 consisting of 312 amino acid residues in molecular based assays yielding definitive prostate cancer diagnosis." The Examiner also states that Applicants failed to disclose a specific, substantial and credible use because Applicants did not disclose a property of the epitope of the claimed polynucleotide. Applicants respectfully traverse the rejection.

Applicants' previous response and arguments presented above with respect to these issues are incorporated herein. Applicants submit that although the Examiner's reasons for the rejection are respectfully traversed, in order to expedite prosecution of the instant claims, the claims have been amended to remove the language referring to fragments of the claimed polynucleotides. Additionally, the claims have been amended to recite the "consisting" language to cover the specific sequence of SEQ ID NO: 4 and its complements. Finally, as pointed out above, in *Noelle*, the Court of Appeals to the Federal Circuit held that

physical properties is one of the way in which an applicant can provide an adequate written description of a biological substance, but it is not the only way. Applicants have provide the exact amino acid residues of SEQ ID NO: 4 which equates to a biological substance's structure, formula or chemical name.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1-4 under 35 U.S.C. § 101.

Rejection of Claims 1-4 Under 35 U.S.C. § 112, First Paragraph

The Examiner also rejects claims 1-4 are rejected under 35 U.S.C. § 112, first paragraph, based on the 35 U.S.C. § 101 rejection above. Applicants' arguments against the 35 U.S.C. § 112, first paragraph above are therefore incorporated herein. Accordingly, Applicants respectfully request withdrawal of this rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph.

CONCLUSION

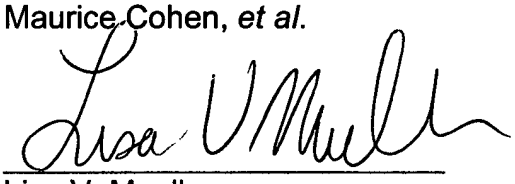
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101 and 112. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

Maurice Cohen, *et al.*



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